

MAR 31 2000

K 992392

510(K) Summary

Date Prepared: June 7, 1999

Name of Contact Person: Ralph J. Flatau

Address: InfiMed, Inc
121 Metropolitan Drive
Liverpool NY 13088

Phone: (315)453-4545 x224

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Device trade name: RTLX

Common name: Digital Imaging System

Classification Name: Extraoral source x-ray system (as per 872.1800)

Device Description:

RTLX, for "Real-Time, Low-Intensity X-ray" is the first X-ray imaging system that provides capabilities for instant, full motion, digital radiographs designed specifically for the dental imaging marketplace. RTLX provides capabilities for X-ray generation, radiograph capture, image storage, and image display at up to 24 fps. The full motion, digital radiographs enhance a clinicians ability for "point-and-view" radiographs reducing patient X-ray exposure and time in the chair and improving speed and accuracy for procedure performance. Product appearance and mechanical structure is designed to provide a user friendly system for sensor placement and video control. In addition, printouts can be made of individual video frames.

The RTLX includes an X-ray source and X-ray sensor assembly for generation and acquisition of X-ray signals. Additionally, power and X-ray control electronics are provided, and an image processor is utilized for radiograph acquisition, processing, and display. Mechanical design emphasizes appearance and functionality. Switches, LEDs, and a printer are provided for user input and feedback.

Intended Use:

The RTLX is a digital dental X-ray system with an intra-oral electronic sensor. Its intended use is to provide real-time x-ray images for dentists with a low X-ray dose. By producing real-time imaging, the RTLX provides immediate information in the course of operative treatment, such as information on the position of instruments in internal structures.

Conclusions drawn from comparison:

The RTLX performs the same functions in the same environment as the predicate devices. The RTLX uses the same sensor technology as the Schick Technologies and the Trophy Radiologie systems and has the same real time image functionality and generator specifications as that of the HDLX system. There are some new features offered with the RTLX, but these are built on the same basic functionality offered by the three predicate devices listed and raise no new questions of efficacy or substantial risk.

Predicate substantially equivalent devices and comparison:

FLUOROSCOPE sensor sensor

Feature/System	Panoramic RTLX	Panoramic HDLX	Schick Technologies CDR	Trophy Radiologie RVG-S
510(k) number	N/A	K943532	K933455	K881133
X-ray Energy Source	70kV/ 100µA	70kV/ 100µA	N/A (X-ray source dependent)	N/A (X-ray source dependent)
Image Acquisition speed (maximum)	24 frames/second	30 frames/second	N/A (Still Frames only)	N/A (Still Frames only)
Display image resolution	128x160 @ 24fps 256x320 @ 6 fps	768 x 494	N/Available	N/Available
Sensor Sizes	20.1 x 30.1 mm	18 mm diameter	25.2 x 36.5 mm 19.2 x 34.6 mm 14.7 x 20.9 mm	18.2 x 27.5
X-ray Image Acquisition Device	CCD Sensor with Scintillator	Image Intensifier with CCD Camera	CCD Sensor with Scintillator	CCD, fiberoptics and scintillator.
Sensor Type	Intraoral Sensor	Intraoral Sensor	Intraoral Sensor	Intraoral Sensor
X-ray Source	Extraoral	Extraoral	Extraoral	Extraoral
"Window / level" features	Yes	Yes	Yes	Yes
Forward / Reverse / Still capability	Yes	Yes (Via attached VCR)	Still only	Still only
Hard copy Capability	Yes	Yes	Yes	Yes
Image Processor/Data Storage	Personal Computer	Personal Computer	Optional Personal Computer	Personal Computer
Disinfection / Sterilization	Cold Sterilization and Disposable sheaths. Cold sterilization using 3.4% gluteraldehde Sheath constructed of low density polyethelene injected with ethyl / methyl acrylate by Banta Healthcare Group (formerly Ling Products (Applied Technology))	Not Specified	Cold Sterilization and Disposable sheaths Sheath constructed of low density polyethelene injected with ethyl / methyl acrylate by Banta Healthcare Group (formerly Ling Products (Applied Technology))	Cold Sterilization and Disposable sheaths. Cold sterilization using 3.4% gluteraldehde Sheath constructed of low density polyethelene injected with ethyl / methyl acrylate by Banta Healthcare Group (formerly Ling Products (Applied Technology))



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Ralph J. Flatau
Quality Assurance Manager
InfiMed, Inc.
121 Metropolitan Drive
Liverpool, NY 13088Re: K992392
InfiMed RTLX Extraoral Dental System
Dated: January 19, 2000
Received: January 21, 2000
Regulatory class: II
21 CFR 872.1800/Procode: 90 MUH

Dear Mr. Flatau:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for *in vitro* diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

Indication for Use

510(K) Number (if known): 992392

Device Name: RTLX

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Concurrence of CDRH, Office of Device Evaluation (DOE)

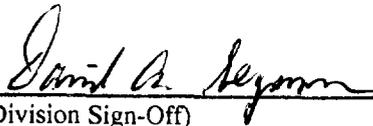
Prescription Use

Or

Over the counter Use

Per 21 CFR 801.109

(Optional format 1-2-96)



(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number 992392